Amendments to the Claims:

1. (Original) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN-β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer in an amount sufficient to maintain the pH of said composition within plus or minus 0.5 units of a specified pH, where the specified pH is about 3.0 to about 5.0, said formulation having an ionic strength that is not greater than about 60 mM.

2. (Original) The composition of claim 1, wherein said buffer is present at a concentration of about 1 mM to about 30 mM.

3. (Original) The composition of claim 2, wherein said buffer is present at a concentration of about 1 mM to about 10 mM.

4. (Original) The composition of claim 3, wherein said buffer is present at a concentration of about 2 mM to about 7 mM.

5. (Original) The composition of claim 4, wherein said buffer is present at a concentration of about 2 to about 5 mM.

6. (Original) The composition of claim 5, wherein said buffer is present at a concentration of about 5 mM.

7. (Withdrawn) The composition of claim 1, wherein said specified pH is about 3.0 and wherein said buffer is glycine.

8. (Original) The composition of claim 1, wherein said specified pH is about 4.0 and wherein said buffer is aspartic acid.

9. (Withdrawn) The composition of claim 1, wherein said specified pH is about 5.0 and wherein said buffer is sodium succinate.

10. (Withdrawn) The composition of claim 6, wherein said specified pH is about 3.0 and wherein said buffer is glycine.

11. (Original) The composition of claim 6, wherein said specified pH is about 4.0 and wherein said buffer is aspartic acid.

12. (Withdrawn) The composition of claim 6, wherein said specified pH is about 5.0 and wherein said buffer is sodium succinate.

13. (Original) The composition of claim 1, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

14. (Original) The composition of claim 1, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

15. (Original) The composition of claim 1, further comprising an amount of a non-ionic tonicifying agent sufficient to render said composition isotonic, wherein said non-ionic tonicifying agent is trehalose.

16. (Original) The composition of claim 15, wherein said trehalose is present at a concentration of about 9% by weight per volume.

17. (Original) The composition of claim 15, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

18. (Original) The composition of claim 15, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

19. (Withdrawn) The composition of claim 10, further comprising an amount of a non-ionic tonicifying agent sufficient to render the composition isotonic, wherein said non-ionic tonicifying agent is trehalose.

20. (Withdrawn) The composition of claim 19, wherein said trehalose is present at a concentration of about 9% by weight per volume.

21. (Withdrawn) The composition of claim 19, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

22. (Withdrawn) The composition of claim 19, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

23. (Original) The composition of claim 11, further comprising an amount of a non-ionic tonicifying agent sufficient to render the composition isotonic, wherein said non-ionic tonicifying agent is trehalose.

24. (Original) The composition of claim 23, wherein said trehalose is present at a concentration of about 9% by weight per volume.

25. (Original) The composition of claim 23, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

26. (Original) The composition of claim 23, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

27. (Withdrawn) The composition of claim 12, further comprising an amount of a non-ionic tonicifying agent sufficient to render the composition isotonic, wherein said non-ionic tonicifying agent is trehalose.

28. (Withdrawn) The composition of claim 27, wherein said trehalose is present at a concentration of about 9% by weight per volume.

29. (Withdrawn) The composition of claim 27, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

30. (Withdrawn) The composition of claim 27, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

31. (Original) The composition of claim 1, wherein said IFN-β is the polypeptide with the amino acid sequence of mature native IFN-β or biologically active variant thereof.

32. (Original) The composition of claim 31, wherein said IFN-β is recombinantly produced.

33. (Original) The composition of claim 32, wherein said IFN-β is glycosylated or unglycosylated.

34. (Original) The composition of claim 33, wherein said IFN-β is unglycosylated human IFN-β (hIFN-β) or biologically active mutein thereof.

35. (Original) The composition of claim 34, wherein said mutein is hIFN-β_{ser17}.

36. (Original) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN-β) or biologically active variant thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer selected from the group consisting of glycine, aspartic acid, or sodium succinate present at a concentration of about 1 mM to about 10 mM, said composition having a pH of about 3.0 to about 5.0, and wherein said formulation has an ionic-strength that is not greater than about 60 mM.

37. (Original) The composition of claim 36, wherein said IFN-β is recombinant human IFN-β (rhIFN-β) or biologically active mutein thereof.

38. (Original) The composition of claim 37, wherein said rhIFN-β or biologically active mutein thereof is unglycosylated.

39. (Original) The composition of claim 38, wherein said mutein is hIFN-β_{ser17}.

40. (Original) The composition of claim 36, wherein said rhIFN-β is present at a concentration of about 0.01 mg/ml to about 20.0 mg/ml.

41. (Withdrawn) The composition of claim 36, wherein said buffer is glycine, said glycine being present at a concentration of about 5 mM, and wherein said composition has a pH of about 3.0.

42. (Withdrawn) The composition of claim 41 further comprising about 9% trehalose by weight per volume.

43. (Original) The composition of claim 36, wherein said buffer is aspartic acid, said aspartic acid being present at a concentration of about 5 mM, and wherein said composition has a pH of about 4.0.

44. (Original) The composition of claim 43 further comprising about 9% trehalose by weight per volume.

45. (Withdrawn) The composition of claim 36, wherein said buffer is sodium succinate, said sodium succinate being present at a concentration of about 5 mM, and wherein said composition has a pH of about 5.0.

46. (Withdrawn) The composition of claim 45, further comprising about 9% trehalose by weight per volume.

47. (Original) The composition of claim 36, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

48. (Original) The composition of claim 36, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

49. (Withdrawn) The composition of claim 41, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

50. (Withdrawn) The composition of claim 41, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

51. (Original) The composition of claim 43, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

52. (Original) The composition of claim 43, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

53. (Withdrawn) The composition of claim 45, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

54. (Withdrawn) The composition of claim 45, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

55. (Withdrawn) The composition of claim 42, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

56. (Withdrawn) The composition of claim 42, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

57. (Original) The composition of claim 44, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

58. (Original) The composition of claim 44, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

59. (Withdrawn) The composition of claim 46, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

60. (Withdrawn) The composition of claim 46, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

61. (Withdrawn) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric human interferon-beta (IFN-β) or biologically active mutein thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises glycine as a buffer, where said buffer is present at a concentration of about 2 mM to about 5 mM, said composition having a pH of about 3.0 to about 4.0, and wherein said formulation has an ionic-strength that is not greater than about 40 mM.

62. (Withdrawn) The composition of claim 61, wherein said rhIFN-β or biologically active mutein thereof is unglycosylated.

63. (Withdrawn) The composition of claim 62, wherein said mutein is hIFN-β_{ser17}.

64. (Withdrawn) The composition of claim 63, wherein said buffer is present at a concentration of about 5 mM, said pH is about 3.0, and said ionic-strength is not greater than about 20 mM.

65. (Withdrawn) The composition of claim 61, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

66. (Withdrawn) The composition of claim 61, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

67. (Withdrawn) The composition of claim 61, further comprising about 9% trehalose by weight per volume.

68. (Original) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric human interferon-beta (IFN-β) or biologically active mutein thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises aspartic acid as a buffer, where said buffer is present at a concentration of about 2 mM to about 5 mM, said composition having a pH of about 3.5 to about 4.5, and wherein said formulation has an ionic-strength that is not greater than about 40 mM.

69. (Original) The composition of claim 68, wherein said rhIFN-β or biologically active mutein thereof is unglycosylated.

70. (Original) The composition of claim 69, wherein said mutein is hIFN-β_{ser17}.

71. (Original) The composition of claim 68, wherein said buffer is present at a concentration of about 5 mM, said pH is about 4.0, and said ionic-strength is not greater than about 20 mM.

72. (Original) The composition of claim 68, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

73. (Original) The composition of claim 68, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

74. (Original) The composition of claim 68, further comprising about 9% trehalose by weight per volume.

75. (Withdrawn) A stabilized HSA-free pharmaceutical composition comprising substantially monomeric human interferon-beta (IFN-β) or biologically active mutein thereof solubilized in a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises sodium succinate as a buffer, where said buffer is present at a concentration of about 2 mM to about 5 mM, said composition having a pH of about 4.5 to about 5.0, and wherein said formulation has an ionic-strength that is not greater than about 40 mM.

76. (Withdrawn) The composition of claim 75, wherein said rhIFN-β or biologically active mutein thereof is unglycosylated.

77. (Withdrawn) The composition of claim 76, wherein said mutein is hIFN-$ß_{ser17}$.

78. (Withdrawn) The composition of claim 75, wherein said buffer is present at a concentration of about 5 mM, said pH is about 5.0, and said ionic-strength is not greater than about 20 mM.

79. (Withdrawn) The composition of claim 75, wherein said composition is a liquid or a dried form, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

80. (Withdrawn) The composition of claim 75, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

81. (Withdrawn) The composition of claim 75, further comprising about 9% trehalose by weight per volume.

82. (Currently Amended) A method for increasing solubility of interferon-beta (IFN-β) or biologically active variant thereof in a pharmaceutical composition in the absence of human serum albumin, said method comprising preparing said composition with a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer in an amount sufficient to maintain the pH of said composition within plus or minus 0.5 units of a specified pH, where the specified pH is about 3.0 to about 5.0, said formulation having an ionic strength that is not greater than about 60 mM, and incorporating said IFN-β or biologically active variant thereof into said composition, wherein said interferon-beta (IFN-β) or biologically active variant thereof within said composition is substantially monomeric.

83. (Original) The method of claim 82, wherein said buffer is present at a concentration of about 1 mM to about 30 mM.

84. (Original) The method of claim 83, wherein said buffer is present at a concentration of about 2 mM to about 5 mM.

85. (Withdrawn) The method of claim 84, wherein said specified pH is about 3.0 and wherein said buffer is glycine.

86. (Original) The method of claim 84, wherein said specified pH is about 4.0 and wherein said buffer is aspartic acid.

87. (Withdrawn) The method of claim 84, wherein said specified pH is about 5.0 and wherein said buffer is sodium succinate.

88. (Original) The method of claim 82, wherein said composition further comprises a non-ionic tonicifying agent in an amount sufficient to render said composition isotonic, wherein said non-ionic tonicifying agent is trehalose.

89. (Original) The method of claim 82, further comprising the step of preparing a dried form of said composition, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

90. (Original) The method of claim 82, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

91. (Original) A pharmaceutical composition produced according to the method of claim 82.

92. (Original) A method for preparing an HSA-free pharmaceutical composition comprising substantially monomeric interferon-beta (IFN-β), said method comprising preparing

said composition with a low-ionic-strength formulation, wherein said low-ionic-strength formulation is a solution that comprises a buffer in an amount sufficient to maintain the pH of said composition within plus or minus 0.5 units of a specified pH, wherein the specified pH is about 3.0 to about 5.0, said formulation having an ionic strength not greater than about 60 mM, and incorporating said IFN-β or biologically active variant thereof into said composition.

93. (Original) The method of claim 92, wherein said buffer is present at a concentration of about 1 mM to about 30 mM.

94. (Original) The method of claim 93, wherein said buffer is present at a concentration of about 2 mM to about 5 mM.

95. (Withdrawn) The method of claim 94, wherein said specified pH is about 3.0 and wherein said buffer is glycine.

96. (Original) The method of claim 94, wherein said specified pH is about 4.0 and wherein said buffer is aspartic acid.

97. (Withdrawn) The method of claim 94, wherein said specified pH is about 5.0 and wherein said buffer is sodium succinate.

98. (Original) The method of claim 92, wherein said composition further comprises a non-ionic tonicifying agent in an amount sufficient to render said composition isotonic, wherein said non-ionic tonicifying agent is trehalose.

99. (Original) The method of claim 92, further comprising the step of preparing a dried form of said composition, wherein said dried form is selected from the group consisting of a lyophilized form, an air-dried form, and a spray-dried form.

100. (Original) The method of claim 92, wherein said composition is an aqueous or nonaqueous solution, an aqueous or nonaqueous suspension, or a dry powder form that is suitable for delivery to a subject by pulmonary inhalation.

101. (Original) A pharmaceutical composition produced according to the method of claim 92.

102. (Original) A formulation for the diagnosis, prevention, or treatment of diseases responsive to therapy with interferon-β (IFN-β), said formulation comprising the pharmaceutical composition according to claims 1, 36, 61, 68, or 75.

103. (New) The composition of claim 8, wherein said aspartic acid is present at a concentration of about 2 mM.

104. (New) The method of claim 96, wherein said aspartic acid is present at a concentration of about 2 mM.

105. (New) The composition of claim 1, wherein said IFN-β is stabilized for at least 2 months at a temperature of 5°C.

106. (New) The composition of claim 1, wherein said IFN-β is stabilized for at least 2 months at a temperature of 30°C.

107. (New) The method of claim 92, wherein said IFN-β is stabilized for at least 2 months at a temperature of 5°C.

108. (New) The method of claim 92, wherein said IFN-β is stabilized for at least 2 months at a temperature of 30°C.